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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,768	02/23/2001	Ekkehard Neuhaus	0147-0215P	3740

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

22

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,768

Applicant(s)

NEUHAUS ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3 and 14-15 are canceled. Claims 1, 4-13 and 16-19 are pending.

Rejection of Claims 1, 4-13, and 16 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

Claims 1, 4-13, and 16 remain and new Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/17/02. Applicant's arguments filed 4/22/03 have been considered but are not deemed persuasive.

Applicant asserts that they have described ADP/ATP translocator nucleotide sequences from plants and bacteria as well as functional features and a test for functionality (response page 4 3rd paragraph). Applicant has only described sequences from *Arabidopsis* in terms of the encoded protein. Neither the potato nor the bacterial sequences are in the sequence listing and the references Applicant cites to support the argument for written description are not incorporated by reference. Furthermore, it is unclear whether the references teach genes or merely enzymes. Further, there is no comparison of 'functional features' as Applicant has asserted. No defining motifs or conserved regions in either the nucleotide or protein sequences have been identified,

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and the nucleotide sequences have not been entered. Moreover, Applicant has not described the sequence relatedness among the sequences Applicant has taught that would define the claimed genus.

Claims 1, 4-13, and 16 remain and new Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the production of a transgenic potato plants transformed with the AATP1-cDNA gene from *Arabidopsis*, exhibiting an increased yield of starch and percent amylose content, does not reasonably provide enablement for a method for the production of a transgenic plant transformed with a foreign nucleic acid molecule of undefined source, length, and function, exhibiting an increased yield of starch and percent amylose content. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/17/02. Applicant's arguments filed 4/22/03 have been considered but are not deemed persuasive.

Applicant asserts that although the Willmitzer reference taught a failed attempt to increase starch in potato, the reference also showed success achieved by Kishore *et al.* in increasing the starch content of tubers, and that the Anderson reference does not teach how isoforms of a starch metabolic enzyme is an unpredictable factor in starch modification via transformation (response page 5, 2nd paragraph). The Willmitzer reference is unambiguous in teaching unpredictability in manipulating starch metabolism by transformation, and page 170 of the Anderson reference from line 4 to the end of the passage clearly refers to the presence of tissue specific expression of either the same gene or different sized and unique isoforms. Further,

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Applicant has not addressed the Examiner's arguments with respect to the polyploidal nature of many high production starch crop plants and the likely presence of multiple isoforms therein, as well as the nature of tissue specific regulation in these plants articulated in the Anderson reference and iterated in the Examiner's rejection. Furthermore, no demonstration of altered oil content in oil-storing or starch-storing plants has been demonstrated.

Applicant asserts that although a large amount of experimentation may be necessary it is not determinative, but rather the determinative factor is whether the experimentation required is undue (response page 6, 2nd paragraph). Applicant further states that because the level of skill is high in the fields of molecular biology and biochemistry, the experimentation is not undue and therefore the invention is enabled (response page 6, 3rd paragraph). However, Applicant cannot rely upon one of skill in the art given the lack of guidance in the specification and the limited scope of Applicant's disclosure with respect to sequences and plants transformed. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 1, 4-13, and 16 remain and new Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/17/02. Applicant's arguments filed 4/22/03 have been considered but are not deemed persuasive. Applicant's amendments have necessitated the rejection of Claims 1 and 10 under 35 U.S.C. 112, second paragraph.

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At Claims 1 and 10, "the genome" is indefinite. It is unclear which plant genome is to be transformed: the plastidial, mitochondrial, or nuclear genome.

At Claims 11, "and/or" is indefinite because it is unclear what is intended.

All claims are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
June 28, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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